No. 92-1979

Supreme Court, U.S.
FILED
AUG 31 1993
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

JANE KING,

Petitioner,

v.

THE COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

In this case, the court of appeals held that all state-law damage claims against the manufacturers of FDA-approved Class III medical devices -- the devices most likely to cause serious injuries to consumers -- are preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, *et seq.* As a result, victims of those devices, such as petitioner Jane King, are left without *any* remedy for their injuries. This case is worthy of review because the federal and state courts are split over the proper interpretation of the MDA's preemption provision, the court of appeals misinterpreted the authoritative views of the Food and Drug Administration ("FDA"), and the issue presented here is manifestly important. Petitioner has now been joined by twenty-eight states and territories in urging that certiorari be granted. *See* Brief of Alabama, *et al.* (filed Aug. 18, 1993).

In its opposition, respondent argues that there is no division among the lower courts, that the FDA's interpretations support the First Circuit's ruling, and that, even if they do not, they should not be followed. As we show below, respondent misinterprets the relevant legal authorities, overlooks others, and

offers no persuasive reason why review should not be granted.

A. Conflicts With Other Decisions.

Respondent insists that there is no conflict between the decision of the court of appeals below and that of the Hawaii Supreme Court in *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (1992). There, a manufacturer argued that the MDA's premarket approval ("PMA") of its Class III device constituted a "requirement" that preempted a damage action under 21 U.S.C. § 360k(a), but the court held that "the statutes and regulations governing pre-market approval set forth general procedural requirements and, therefore, do not trigger preemption analysis under [21 C.F.R.] § 808.1(b)." *Larsen*, 837 P.2d at 1282. As the attorneys general of twenty-eight states and territories, including Hawaii, have recognized, this ruling squarely conflicts with the decision of the court of appeals in this case. *See* Brief of Alabama, *et al.* 16-17 & n.6.

Admittedly, after rejecting preemption on the basis of the PMA requirements, *Larsen* also refused to preempt the plaintiff's claims on the ground that the devices were approved for marketing only under the FDA's truncated "substantial equivalence" procedures. But under the First Circuit's analysis, which tied preemption of all but petitioner's fraud-based claims to the FDA's approval of respondent's labeling (13a, 18a), this secondary holding also irreconcilably conflicts with the decision below, because, even in "substantial equivalence" cases, the FDA considers the manufacturer's proposed labeling. *See* Pet. 13 n.7.

Respondent also misses the mark when it attempts to distinguish the MDA preemption cases involving hearing aids and tampons (*see* Pet. 15-17 & n.10), on the ground that those devices are covered under somewhat different regulatory regimes. The important point for preemption purposes -- which respondent nowhere addresses -- is that in those cases the courts narrowly applied the term "requirement" in 21 U.S.C. § 360k(a), finding preemption only where the FDA's regulations or the MDA itself demanded a specific warning or other regulatory requirement that could not be changed *and* the state was attempting to regulate in that precise area. Here, there are no "requirements" concerning respondent's alleged inadequacies in the manufacture, testing, or design of its collagen implants and, thus, there is no preemption of

petitioner's causes of actions based on those claims.[1] The same analysis applies to petitioner's duty to warn and misbranding claims. Although the FDA passed on the labeling supplied to it by respondent, there is no required regulatory warning for collagen implants and, more importantly, respondent was free to add warnings without prior FDA approval, *see* 21 C.F.R. § 814.39(d), a fact which respondent ignores. *See also* Brief of Alabama, *et al.* 7-8.

Despite respondent's protestations to the contrary (Opp. 9), the court of appeals' ruling runs afoul of this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), which requires the courts to give separate consideration to each claim that is alleged to be preempted. That analysis is directly contrary to the one employed below, which, while purporting to follow *Cipollone*, preempted petitioner's claims because the FDA had passed on respondent's labeling (11a, 13a), even though most of her claims were not based on a duty to warn.

The incompatibility of the First Circuit's decision with *Cipollone* is nowhere more evident than in its treatment of petitioner's fraud and misrepresentation claims, which have no conceivable corollary in any MDA "requirement" or specific PMA condition applicable to respondent's product. Rather, as in *Cipollone*, those claims are not preempted because they are grounded on a general duty not to deceive, not any obligation under the MDA. 112 S.Ct. at 2623-24; *see also* 21 C.F.R. § 808.1(d)(1)(no preemption under MDA where claim relates to general duty applicable to "other products in addition to devices...").

Respondent makes little attempt to defend preemption of petitioner's fraud claims on its merits, but tries to create ambiguity in the court of appeals' decision where none exists. A majority of the panel, Senior Judges Aldrich and Campbell, held that the fraud and misrepresentation claims were preempted (19a-20a), and while

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[1] Although respondent repeatedly asserts that the pre-market approval in this case contained "detailed requirements" for the design of respondent's product (Opp. at 2; *see also id.* at 3, 6), there are no FDA or MDA design requirements of any kind for collagen implants generally, or respondent's product specifically, as evidenced by respondent's failure to cite any authority for its claim.

Judge Tourrella rejected the fraud claim on state-law grounds (11a), he also did so on federal preemption grounds (*id.*), a fact which respondent omits. Thus, it is clear that any claim that a PMA was obtained through fraud is preempted under the law in the First Circuit. That holding, as well as the court of appeals' other preemption rulings, warrant this Court's attention, because of their evident incompatibility with *Cipollone* and decisions of other state and federal courts.[2]

B. The Inapplicability of MDA Preemption to Damage Actions and FDA's Authoritative Views.

The petition also argued that review should be granted because the MDA's preemption provision, 21 U.S.C. § 360k(a), was not intended by Congress to preempt damage claims. Section 360k(a) speaks of a "State or political subdivision of a State ... establish[ing] or continu[ing] in effect" device requirements, which cannot reasonably be construed as referring to a jury's award in a damage action. Nonetheless, respondent relies principally on *Cipollone*, which held that, in some circumstances, the term "requirement" can include a common law duty, 112 S. Ct. at 2619-20, although, as we have explained (Pet. 21-24), *Cipollone* involved a statute whose overall preemption language is very different from that of the MDA.[3]

The question of whether the term covers damage actions depends on its context in the operative statute. Section 360k(a)

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[2] Respondent claims that the Fifth Circuit's decision in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. pending*, No. 92-1989 (filed June 16, 1993), finding preemption in another collagen case, evidences "growing unanimity" (Opp. 6), and that, therefore, review should be denied. The foregoing discussion demonstrates that judicial views of MDA preemption are anything but unanimous. We note as well that, in *Cipollone*, this Court granted certiorari even though all the courts of appeals that had considered the issue found all of plaintiffs' claims preempted. 112 S. Ct. at 2613 n.2.

[3] Respondent simply errs in stating that "[e]very lower federal court to have addressed the question since *Cipollone*" (Opp. 7) has concluded that a "requirement" includes common law claims for preemption purposes. *See MacDonald v. Monsanto Co.*, 813 F. Supp. 1258, 1260-61 (E.D. Tex. 1993)("requirement" under preemption provision of Federal Insecticide, Fungicide, and Rodenticide Act does not include common law claims); *Couture v. Dow Chemical U.S.A.*, 804 F. Supp. 1298, 1301-03 (D. Mont. 1992)(same).

uses the word "requirement" several times; in subsections (a)(1) and (a)(2) of 21 U.S.C. § 360k, the statute refers to a "any requirement applicable under this Act," which is a clear reference to statutory and regulatory specifications for devices themselves under the MDA, not to damage remedies. In the introductory paragraph of section 360k(a), referring to the actions of states and their political subdivisions, the term is also used, and there is no reason to believe that Congress meant it to be used differently there. *See Sutherland Statutory Construction* § 47.16, p. 161 (Sands 4th ed. 1984)(multiple uses of same word ought to be accorded same meaning); *see also* Pet. 21 & n.3 (legislative history supports petitioner's interpretation).

It is this use of "requirement" in subsection (b) of § 360k on which the petition also relied (Pet. 23-24). That provision allows the FDA to exempt certain requirements from preemption, and obviously applies only to the legislative and regulatory enactments of state and local governments, not, as respondent asserts (Opp. 13 n.5), to state-law damage claims. Thus, the meaning of "requirement" in subsection (b) strongly indicates that subsection (a)'s preemption language, which uses the same term, is similarly limited. Indeed, the only court to have specifically addressed the question of whether subsection (b), and thus subsection (a), could apply to damage claims, labeled the idea "absurd." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *see also* Pet. 24 n.16 (citing other relevant cases); *cf.* Brief of Alabama, *et al.* 14.

Finally, respondent misstates the FDA's views on MDA preemption. For the most part, we rely on our initial discussion (Pet. 21-22 & nn. 13-15), which explains that the FDA's regulations, regulatory commentary, and other authoritative pronouncements refer repeatedly to the preemption of certain state and local positive enactments, do not even suggest the possibility of preemption of damage awards, and, indeed, on several occasions, indicate that such awards would not be preempted because they are premised on duties that "relate[] to other products in addition to devices ... ." 21 C.F.R. § 808.1(d)(1).

A few points made by respondent do require a response, however. First, the fact that a "court decision" may be subject to preemption, *see id.* § 808.1(b), is of no consequence. As we have

stated (Pet. 21), a "court decision" interpreting a state regulation, like the regulation itself, could be preempted in some circumstances. This is precisely why, when considering whether to grant an exemption to preemption, or whether there is preemption at all, the FDA requires the states and localities to submit "any statute, rule, regulation or ordinance," along with any "judicial or administrative interpretations [thereof]." *Id.* § 808.20(c)(1); *see also id.* § 808.20(d). In short, the fact that preemption of state and local laws should be considered in conjunction with "court decisions" interpreting them does nothing to undermine the FDA's view that tort claims are not preempted by the MDA.

Second, respondent sidesteps the importance of the FDA's rule that preemption applies only to state and local requirements that are specifically about devices, not general legal duties, 21 C.F.R. § 808.1(d)(1), by stating that this is only true when those duties do not apply to substantive requirements applicable to devices. Opp. 12 n.8. This makes no sense, because if a damage action alleging warranty claims under the Uniform Commercial Code, or a fraud claim under a state unfair trade practice act, *see* 21 C.F.R. § 808.1(d)(1), does not involve a substantive requirement applicable to a device, it could not possibly be preempted and FDA would not have to say so. *See* Pet. 15 n.8. The clear purpose of § 808.1(d)(1) is to limit preemption to state and local requirements that apply *only* to devices, not to general duties imposed by state law that apply to devices as well as other products.

Finally, respondent ends its discussion of the FDA's views with citations to regulatory commentary which, it implies, supports the view that pre-market approval of a Class III device, standing alone, preempts all state law concerning those devices, including damage claims (Opp. 8-9). However, that commentary stands for an entirely different proposition: once FDA requires pre-market approval of a specific device, state or local governments may be precluded from enforcing their own PMA procedures as to that device. Indeed, the commentary strongly indicates that MDA preemption applies in a quite limited way and only to the regulatory programs of the states, not to damage claims. *See* 45 Fed. Reg. 67321, 67323, col. 1 (Oct. 10, 1980); 43 Fed. Reg. 18661, 18664, col. 1 (May 2, 1978).

C. The Manifest Importance of the Decision Below.

Respondent does not dispute the importance of the decision below, other than to suggest that some consumers injured by Class III medical devices might have recourse against persons other than manufacturers, such as doctors. Respondent also asserts that consumers may have state-law claims for violation of the FDCA (Opp. 14 n.10, *but see* Opp. 9 n.5), which is ironic here because petitioner *did* argue that respondent's device was misbranded within the meaning of the FDCA, and the court of appeals held that claim preempted also (10a, *citing* 21 U.S.C. § 352(a)(FDCA misbranding)).

Respondent does not even attempt to explain away the view of the former FDA Chief Counsel that this case is "probably the single most important case to the medical-device industry in American history." *See* Pet. 3.[4] Now that twenty-eight states and territories have taken the rare step of filing a brief in this purely private case, urging the Court to grant the petition, there can be little doubt that this case is of great concern not only to American consumers, but to their governmental protectors, largely because it will leave victims with no remedy at all. *Compare, e.g., English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990)(presumption against preemption especially weighty where Congress has not provided judicial recourse); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)(same).

Conclusion

The petition for writ of certiorari should be granted.

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[4] *See also, e.g.*, Linda Himmelstein, *An Invincible Shield for Medical Manufacturers -- The Courts May Ban Lawsuits Over Devices Approved by the FDA*, Business Week, Aug. 9, 1993, at 73.

Respectfully submitted,

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August 31, 1993